

**UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION**

JEFFREY THELEN,

Plaintiff,

v.

Case No. 8:20-cv-1724-TPB-JSS

SOMATICS, LLC, and
ELEKTRIKA, INC.,

Defendants.

**ORDER GRANTING IN PART AND DENYING IN PART
DEFENDANT ELEKTRIKA’S MOTION TO DISMISS**

This matter is before the Court on “Elektrika, Inc.’s Motion to Dismiss Plaintiff’s Complaint,” filed November 16, 2020. (Doc. 24). Plaintiff filed his response in opposition on November 30, 2020. (Doc. 30). After reviewing the motion, response, court file, and record, the Court finds as follows:

Background¹

From May 16, 2014 to July 27, 2016, Plaintiff Jeffrey Thelen underwent 92 sessions of Electroconvulsive Therapy (“ECT”) using the Thymatron System IV device in Omaha, Nebraska. This ECT device was manufactured by Elektrika and supplied to Somatics which, in addition to also manufacturing the ECT device,

¹ The Court accepts as true the facts alleged in the complaint for purposes of ruling on the pending motion to dismiss. See *Erickson v. Pardus*, 551 U.S. 89, 94 (2007) (“[W]hen ruling on a defendant’s motion to dismiss, a judge must accept as true all of the factual allegations contained in the complaint.”). The Court is not required to accept as true any legal conclusions couched as factual allegations. See *Papasan v. Allain*, 478 U.S. 265, 286 (1986).

promotes and distributes the device. Plaintiff alleges that undergoing ECT treatment with this device caused permanent neurological damage impairing his ability to memorize, retain, and recall information. Plaintiff further alleges that despite knowing of the substantial risks associated with ECT treatment, Somatics and Elekrika manufactured and distributed the device and failed to warn Plaintiff of those risks.

On July 24, 2020, Plaintiff filed a seven-count complaint against Somatics and Elekrika, alleging: negligence (Count I), strict liability (Count II), breach of implied warranty of merchantability (Count III), breach of implied warranty of fitness (Count IV), breach of express warranty (Count V), violation of the Nebraska Consumer Protection Act (“NCPA”) (Count VI), and fraudulent misrepresentation (Count VII). Plaintiff seeks punitive damages.

Legal Standard

Federal Rule of Civil Procedure 8(a) requires that a complaint contain “a short and plain statement of the claim showing the [plaintiff] is entitled to relief.” Fed. R. Civ. P. 8(a). While Rule 8(a) does not demand “detailed factual allegations,” it does require “more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do.” *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). In order to survive a motion to dismiss, factual allegations must be sufficient “to state a claim to relief that is plausible on its face.” *Id.* at 570.

When deciding a Rule 12(b)(6) motion, review is generally limited to the four corners of the complaint. *Rickman v. Precisionaire, Inc.*, 902 F. Supp. 232, 233

(M.D. Fla. 1995). Furthermore, when reviewing a complaint for facial sufficiency, a court “must accept [a] [p]laintiff’s well pleaded facts as true, and construe the [c]omplaint in the light most favorable to the [p]laintiff.” *Id.* (citing *Scheuer v. Rhodes*, 416 U.S. 232, 236 (1974)). “[A] motion to dismiss should concern only the complaint’s legal sufficiency, and is not a procedure for resolving factual questions or addressing the merits of the case.” *Am. Int’l Specialty Lines Ins. Co. v. Mosaic Fertilizer, LLC*, 8:09-cv-1264-T-26TGW, 2009 WL 10671157, at *2 (M.D. Fla. Oct. 9, 2009) (Lazzara, J.).

Analysis

In its motion, Elekrika reiterates arguments its co-Defendant Somatics brought in its motion to dismiss and argues several new grounds for dismissal. (Doc. 15). Specifically – in addition to arguments previously raised by Somatics – Elekrika contends: (1) Plaintiff’s claims are impliedly preempted, and (2) Counts III and IV should be merged with Count II. As the Court has already addressed Somatics’ arguments – and dismissed Counts VI and VII – this Order is restricted to Elekrika’s remaining arguments. *See* (Doc. 40).

Preemption

Elekrika first argues Plaintiff’s claims are implicitly preempted by the Food Drug and Cosmetic Act (“FDCA”) and the Medical Device Amendments (“MDA”). Plaintiff disagrees, contending that his state-law tort claims are not preempted.

Implied preemption here is governed by 21 U.S.C. § 337(a), which requires that all actions to enforce FDA requirements “shall be by and in the name of the

United States.” *See McClelland v. Medtronic, Inc.*, 944 F. Supp. 2d 1193, 1200 (M.D. Fla. 2013). The Supreme Court has interpreted this statute as allowing private individuals to bring state-law tort claims, so long as they do not seek to enforce a duty owed to the FDA. *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 353 (2001); *see also Mink v. Smith & Nephew, Inc.*, 860 F.3d 1319, 1327 (11th Cir. 2017).

In this case, Counts II-V are strictly state-law claims that do not seek to enforce FDA requirements. Therefore, these claims are not implicitly preempted. In Count I (negligence), however, Plaintiff presents multiple theories as to why ElektriKA was negligent, some of which may be construed as violating FDA obligations. Nevertheless, further discovery and argument by the parties are needed to determine whether Plaintiff’s negligence claim is preempted. *See Bausch v. Stryker Corp.*, 630 F.3d 546, 559 (7th Cir. 2010). ElektriKA’s motion to dismiss based on implied preemption is, therefore, denied at this time.²

Merger

Next, ElektriKA argues that, if the Court finds Nebraska law governs Count III (implied warranty of merchantability), and Count IV (implied warranty of fitness), those claims should be dismissed because implied warranty claims are subsumed into strict liability claims. In its February 26, 2021, Order, the Court found Nebraska law applies to these claims. *See* (Doc. 40 at 5-7). The Supreme

² The Court notes that, upon further review of Somatics’ arguments in its Motion to Dismiss (Doc. 15), this holding applies to Count I as against both ElektriKA and Somatics. However, as the result is the same under both express and implied preemption, no further action is required.

Court of Nebraska has unequivocally stated breach of implied warranty claims are merged with strict liability claims. *See Freeman v. Hoffman*, 618 N.W. 2d 827, 842-44 (Neb. 2000). As such, the motion is granted as to this ground. Counts III and IV are hereby dismissed.

Accordingly, it is

ORDERED, ADJUDGED, and DECREED:

(1) “Elektrika, Inc.’s Motion to Dismiss Plaintiff’s Complaint” (Doc. 24) is hereby

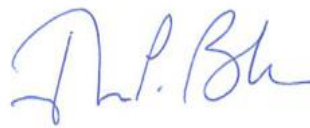
GRANTED IN PART and DENIED IN PART.

(2) The motion is **GRANTED** to the extent that Counts III and IV are merged into Count II.

(3) Counts III and IV are **DISMISSED**.

(4) The motion is otherwise **DENIED**.

DONE and ORDERED in Chambers, in Tampa, Florida, this 31st day of March, 2021.



TOM BARBER
UNITED STATES DISTRICT JUDGE